

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on December 9, 2009. The Office Action provided a three-month shortened statutory period in which to respond, ending on March 9, 2010. Accordingly, this Amendment is timely submitted. Applicant does not believe there to be any fees due herewith this Amendment. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3717519-00723 on the account statement.

Claims 1-11 are currently pending. In the Office Action, Claims 4-11 are objected to. Claims 1-11 are rejected under 35 U.S.C. §§101, 112, 102 and 103. In response, Claims 1-3 and 5-11 have been amended and Claim 4 has been canceled without prejudice or disclaimer. These amendments do not add new matter. The amendments are supported in the specification at, for example, page 2, lines 10-18; page 4, line 37-page 5, line 8. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form because the Patent Office asserts that a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple claim. See, Office Action, page 2, lines 10-13. The Patent Office further asserts that, because of the objection, Claims 4-11 have not been further treated on the merits. See, Office Action, page 2, lines 10-13. In response, Applicant notes that Claims 4-11 have been amended to delete any multiple claim dependencies. For at least the reasons set forth above, Applicant submits that Claims 4-11 fully comply with the requirements under 37 CFR 1.75(c).

Accordingly, Applicant respectfully requests that the objection to Claims 4-11 be reconsidered and withdrawn and that Claims 4-11 be considered on the merits and in view of this Amendment.

In the Office Action, Claims 1-3 are rejected under 35 U.S.C. §101 because the Patent Office asserts that the claimed recitation of a use, without setting forth any steps involved in the process results in an improper definition of a process, i.e., results in a claim which is not a proper process claim. See, Office Action, page 2, line 23-page 3, line 1. In response, Applicant has amended independent Claim 1 to recite, in part, a method comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones or meat extract. The amendment does not add new matter and is supported in the specification at, for example, page 2, lines 10-18. For at least the reasons set forth above, Applicant submits that Claims 1-3 fully comply with the requirements under 35 U.S.C. §101.

Accordingly, Applicant respectfully requests that the rejection of Claims 1-3 under 35 U.S.C. §101 be reconsidered and withdrawn.

In the Office Action, Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite because the Patent Office alleges that “the claim does not set forth any steps involved in the method/process.” See, Office Action, page 3, lines 18-22. In response, and as discussed above, independent Claim 1 has been amended to recite, in part, a method comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones or meat extract. As such, Applicant respectfully submits that Claim 1 positively recites a method step of “administering an oral composition” to a human or an animal. For at least the reasons set forth above, Applicant submits that Claims 1-3 fully comply with the requirements under 35 U.S.C. §112, second paragraph.

Accordingly, Applicant respectfully requests that the rejection of Claims 1-3 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1-3 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 7,374,753 to Farmer et al. (“*Farmer*”). Claims 1-3 were also rejected under 35 U.S.C. §103(a) as being unpatentable over *Farmer*. Applicant respectfully submits that *Farmer* is deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones or meat extract. The amendment does not add new matter and is supported in the

specification at, for example, page 4, line 37-page 5, line 8. Applicant has surprisingly found that by ingesting meat extracts together or not with peptones, or peptones alone, individuals suffering from infection by pathogens as evidenced by intestinal disorders such as, for example, failure of gut epithelial integrity and diarrhea, have a normalized fluid secretion, a cellular structure less damaged, and a decreased inflammation compared to individuals having the same disorders, but a diet not supplemented with meat extracts or peptones. See, specification, page 5, lines 20-25. Applicant respectfully submits that *Farmer* fails to disclose or suggest each and every element of the present claims.

For example, *Farmer* fails to disclose or suggest a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones or meat extract, as required, in part, by the present claims. *Farmer* also fails to disclose or suggest the effects of endotoxin-producing pathogens, as required, in part, by the present claims, and as is admitted by the Patent Office. See, Office Action, page 4, line 25. Instead, *Farmer* is entirely directed to the use of compositions including a lactic acid bacteria for administration to the intestinal tract for inhibiting infections including Sudden Infant Death Syndrome ("SIDS"). At no place in the disclosure does *Farmer* consider the use of compositions having peptones and/or meat extracts, let alone compositions having peptones and/or meat extracts in the presently claimed volumetric amounts. Indeed, the Patent Office does not even use the words "peptone" or "meat extract" with respect to *Farmer* at any place in the Office Action and, thus, fails to point to any portion of *Farmer* that discloses same. For at least the reasons set forth above, Applicant submits that *Farmer* fails to disclose or suggest each and every element of the present claims. Thus, Applicant submits that Claims 1-11 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicant respectfully requests that the rejection of Claims 1-3 under 35 U.S.C. §§102 and 103 be reconsidered and withdrawn.

In the Office Action, Claims 1-3 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1 and 5 of co-pending U.S. Serial No. 10/595,396. The Patent Office asserts that, although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims in both applications are drawn to similar oral compositions. See, Office Action, page 5, lines 21-33.

In response, Applicant submits that, at this stage in prosecution, it would be premature to file a terminal disclaimer because the instant claims have not yet been allowed, and thus, the final version of these claims is not yet known. Further, Applicant also submits that the claims of co-pending U.S. Serial No. 10/595,396 may also be amended to include subject matter not contained in the claims of the present application. At such time when the claims of any of the pending applications become allowed, Applicant will reassess the double patenting rejection in view of the allowed claims.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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